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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,020

03/27/2003

Amarjit Singh

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02/07/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/089,020

Applicant(s)

SINGH ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,15,19 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,15,19 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/29/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see paper, filed 10/31/07, with respect to the rejection(s) of claim(s) 1,2,4-11,15 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,4-11,15 no longer remain rejected under 35 U.S.C. 103(a) as being unpatentable over Skinhoj (WO 99/12524; 3/18/99). New claims 18,19 and 25 are added to this rejection. Skinhoj teaches a composition of an NSAID for peroral use comprising a fast release layer and an extended release layer, wherein said NSAID is present in both layers and in an amount ranging from 1 to 1600 mg. Skinhoj teaches that such a composition reduces the dose amount of active required on a daily bases as compared to a plain tablet. Skinhoj teaches that the composition can comprise a control release material such as cellulose derivatives, and excipients, plasticizers, calcium carbonate and fatty acids. Skinhoj teaches that the composition can exist in tablet form. Skinhoj teaches a number of NSAIDs including nimesulide. Skinhoj teaches that the fractions (fast release layer and extended release layer) can be coated. See abstract, page 9 lines 17-33, page 19 line 22 – page 20 line 27, page 21 lines 19-21, page 26

lines 28-29, page 35 lines 15-24, page 36 line 25 – page 38 line 32, claims 1, 11.

Skinhoj does not disclose an example where nimesulide is employed in the composition / tablet. It would have been obvious to one having ordinary skill in the art to have employed nimesulide in the tablet / composition. One would have been motivated to do this in order to decrease the dosage amount of nimesulide given to a patient.

Response to Applicants' argument

Applicant argues that Claims 1 and 11 have been amended to define the immediate release layer and controlled release layer as single unit layers. However, WO 99/12524 discloses the first and second fractions comprise multiple units and a tablet of single units layers is not obvious from a reference (WO '524) that discloses fractions that comprise multiple units such as pellets. Examiner argues that multiple units are excluded from the instant invention since the instant invention employs "consisting of" language.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 15 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2,15 and 25 recites the limitation "composition ... comprises" in claim 2 line 2 and claim 25 line 2. There is insufficient antecedent basis for this limitation in the claim.

Note claim 1 from which claims indirectly / directly depend recites "composition ... consisting of".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4,5,7-10,15,19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "combination" in claims presents new matter.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "achieve mucoadhesion" in the claim presents new matter. The phrase "extended layer ... having *affinity for gastrointestinal mucosa*" appears to be new matter.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "gas-generating", "acidic substance" and "achieve flotation" in the claim presents new matter.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "lubricants" in the claim presents new matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,4-11,15,19 and 26-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11/545718. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions make claim to a control release pharmaceutical composition comprising immediate release and extended release fractions comprising nimesulide. See USAN '718 claim 11. Both inventions makes claim to the composition comprising substances such as cellulose, pH modifiers, citric acid, fats. USAN '718 claims that the pharmaceutical composition can exist in tablet form. See USAN '718 claims 11 and 12. The instant claims differ from the claims in USAN '718 in that instant claims are limited to the pharmaceutical composition existing only as a tablet, whereas claims in USAN '718 discloses that the composition can exist in a variety of physical forms including tablets. Since USAN '718 makes claim that the composition can exist as a tablet, the instant claims are made obvious over USAN '718.

Claims 1,2,4-11,15,19 and 26-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/978162. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions make claim to a control release pharmaceutical composition comprising immediate release

and extended release fractions comprising nimesulide. Both inventions makes claim to the composition comprising substances such as cellulose, pH modifiers, citric acid, fats. USAN '162 claims that the pharmaceutical composition can exist in tablet form. See USAN '162 claims 10 - 12. The instant claims differ from the claims in USAN '162 in that instant claims are limited to the pharmaceutical composition existing only as a tablet, whereas claims in USAN '162 discloses that the composition can exist in tablet form. Since USAN '162 makes claim that the composition can exist as a tablet, the instant claims are made obvious over USAN '162.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objection

Claims 20-24 are no longer objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are now rejected based on the discussion above.

Telephonic Inquiry

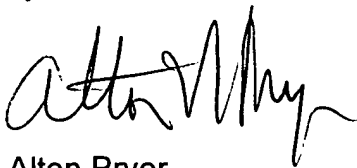
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Alton Pryor', with a stylized flourish at the end.

Alton Pryor
Primary Examiner
AU 1616